



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DATE: March 22, 2018

SUBJECT: Science Review in Support of the Registration of FAL-3100 with 3.3% 1-Methylcyclopropene (1-MCP) as its Active Ingredient

Type of Data Review: Product Chemistry, Mammalian Toxicology
Decision Number: 535565
DP Number: 444149
EPA File Symbol Number: 62097-LE
Chemical Class: Biochemical
PC Code: 224459
Tolerance Exemptions: 40 CFR § 180.1220
MRID Nos.: 50405001-03

FROM: Sadaf Shaukat, Biologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Senior Scientist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, likely belonging to Russell S. Jones, is positioned to the right of the "THROUGH:" line.

And

Catherine Eiden, Senior Advisor
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, likely belonging to Catherine Eiden, is positioned to the right of her name.

TO: James Parker, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

SciReg Inc., on behalf of Fine Agrochemicals has submitted an application for the registration of an end-use product (EP) 62097-LE with 3.3% 1-Methylcyclopropene (1-MCP). This is a post-harvest tool for counteracting undesirable effects of both internal and external sources of ethylene on harvested fruit and vegetables.

EXECUTIVE SUMMARY

FAL-3100 (EPA Reg. No. 62097-LE) is an end-use product, containing 3.3% 1-MCP as its active ingredient. Under normal environmental conditions, the active ingredient methylcyclopropene is a gas. When the product is mixed with water or a buffer solution, it releases the gas 1-MCP. The end-use product is manufactured by an integrated process.¹

EPA has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. Risk to applicators is mitigated as long as the product being registered at this time is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to label instructions. The Agency has considered 1-MCP in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effects from the use of this product.²

STUDY SUMMARIES

Note: DER was created for product chemistry data.

Product Chemistry (MRID 50405001-02)

Test Material: 1-Methylcyclopropene (1-MCP)

PRODUCT IDENTITY AND COMPOSITION (OCSPP 880.1100): This application is for an end-use product called FAL-3100. This is a post-harvest tool for counteracting undesirable effects of both internal and external sources of ethylene on harvested fruit and vegetables. The active ingredient in this product (w/w) is 3.3% 1-MCP. [REDACTED]. The CSF and product label are in agreement regarding the content of active ingredient in the product. The active ingredient name given on the product label

¹ U.S. Environmental Protection Agency, May 2008. Biopesticides Registration Action Document: 1-MCP. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-224459_30-May-08.pdf

² U.S. Environmental Protection Agency, May 2008. Biopesticides Registration Action Document: 1-MCP. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-224459_30-May-08.pdf

matches the name given on the CSF. The CAS Nos. for the active ingredient and impurities are provided on the CSF. The density, pH, and flash point boxes on the CSF are filled in, and the CSF is signed.

I. DESCRIPTION OF STARTING MATERIALS AND FORMULATION PROCESS (OCSP 880.1200):

A description of the starting materials and formulation process was provided in the registrant's latest submission, along with a description of the quality control measures taken during the process in MRID 50405001.

II. DISCUSSION OF FORMATION OF IMPURITIES (OCSP 880.1400): A discussion of the formation of impurities was provided in the registrant's latest submission in MRID 50405001. There are no impurities of toxicological concern in this product.

III. PRELIMINARY ANALYSIS (OCSP 830.1700): A discussion of the preliminary analysis was provided in the registrant's latest submission in MRID 50405002. See DER for more details.

IV. CERTIFIED LIMITS (OCSP 830.1750)

TABLE 1. Nominal CSF concentrations and certified limits for FAL-3100					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Upper	Lower
Active Ingredient					
1-Methylcyclopropene (3100-04-7)	224459	Active ingredient	3.30	3.47	3.13

V. ENFORCEMENT ANALYTICAL METHOD (OCSP 830.1800): The registrant wishes to bridge this data from already registered products (MRID's 45458601-02) since the method is the same. See DER for more details

VI. PHYSICAL AND CHEMICAL PROPERTIES: Table 2 summarizes the physical and chemical properties of the product the registrant wishes to bridge data from (EPA Reg. No.# 71297-2).

TABLE 2. Physical and chemical properties for FAL-3100 (Taken from MRID 45458603)	
GUIDELINE	VALUE/DESCRIPTION
830.6302; Color	White
830.6303; Physical state	Powder
830.6304; Odor	None
830.6315; Flammability	N/A (no combustible liquids)
830.6317; Storage Stability	Data Gap; Registrant must submit storage stability

	results upon completion of study in order to complete registration terms
830.6319; Miscibility	N/A (not a liquid)
830.6320; Corrosion Characteristics	Data Gap; Registrant must submit corrosion results upon completion of study in order to complete registration terms
830.7000; pH	5.7 as a 1% solution in water
830.7050; UV/vis	The absorption spectra in neutral, acidic, and alkaline media did not exhibit maxima; the molar absorption coefficient & bandwidth could not be calculated
830.7100; Viscosity	N/A (not a liquid)
830.7200; Melting Point	No indication of a defined melting point between 25°C-400°C; Using thermal analysis, the 1-MCP formulation did not melt below its decomposition temperature
830.7220; Boiling Point	N/A (solid)
830.7300; Bulk Density	Pour density = 0.27 g/ml @ 20°C Tap density = 0.38 g/ml @ 20°C
830.7520; Particle size, fiber length, and diameter distribution	N/A (not a fibrous test substance)
830.7950; Vapor Pressure	N/A (solid)

MAMMALIAN TOXICOLOGY

The registrant requests to bridge acute mammalian toxicity data from older 1-MCP registered products. The subchronic studies were performed on a similar TGAI that the registrant requests to bridge from.

Study	Species	Results	Toxicity Category	MRID
Acute Oral Toxicity, 870.1100	Rat (male and female albino)	>5000 mg/kg	IV	44464704
Acute Dermal Toxicity, 870.1200	Rat (male and female Crl CD-BR rats)	>5000 mg/kg	IV	45458604
Acute Inhalation Toxicity, 870.1300	Rat (male and female albino)	>165 mg/L	IV	44464706
Primary Dermal Irritation, 870.2500	Rabbit (New Zealand White)	Slightly irritating	IV	45458605
Primary Eye Irritation, 870.2400	Rabbit (New Zealand White)	Conjunctival effects in all rabbits at 1 hr, 4 rabbits in 24 hrs, 1 rabbit in 48 hrs; all cleared by 72 hrs	III	45458606
Skin Sensitization,	Guinea pigs	Not a sensitizer	Not a	45458607

870.2600			sensitizer	
90-Day Oral Toxicity, 870.3100		Data Waiver requested based on the following: 1) physical form is a gas; 2) absence of human exposure from intended use inside air-tight storage room 3) low-likelihood of repeated oral exposure to humans via oral route; 4) low toxicity of 1-MCP	WAIVED	50405003
90-Day Dermal Toxicity, 870.3250		Data waiver requested based on the following: 1) physical form is a gas; 2) absence of human exposure from intended use inside air-tight storage room	WAIVED	50405003
90-Day Inhalation Toxicity, 870.3465		NOEL = 20 ppm		45609001
Prenatal Development, 870.3700		NOEL = 100 ppm		45458608
Bacterial Reverse mutation test, 870.5100		No increase in revertants compared to negative control with and without metabolic activation: not mutagenic in this assay		45380302
In vitro mammalian cell assay, 870.5300/5375		Negative for inducing chromosomal aberrations with and without metabolic activation		45380304

NONTARGET ORGANISM TOXICOLOGY

The registrant requests to bridge nontarget organism toxicity data from older 1-MCP registered products.

Study	Species	Results	Toxicity Category	MRID
Avian Acute Oral Toxicity, 850.2100		Data waiver requested based on the following: 1) Physical form is a gas; 2) Indoor usage in an air-tight storage room; 3) Air emission	WAIVED	50405003

RECOMMENDATIONS AND CONCLUSIONS

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1-Methyleyclopropene
PC Code: 224459

DP Number: 444149
EPA Reg. No.: 62097-LE

- a. The registrant submitted new waiver requests to fulfill the data requirements. (see data matrix)

Confidential Appendix

TABLE 1. Nominal CSF concentrations and certified limits for FAL-3100					
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Active Ingredient					
1-Methylcyclopropene (3100-04-7)	224459	Active ingredient	3.30	3.47	3.13

cc: Sadaf Shaukat R Jones, C Eiden, J Parker, BPPD Science Review File, Manying Xue/HHAD/ARS;